BEFORE THE ENVIRONMENTAL PROTECTION AGENCY

Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA § 6(a)

[EPA-HQ-OPPT-2016-0231; EPA-HQ-OPPT-2016-0742]

Comments of the

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TABLE OF CONTENTS

HSIA Comments on Methylene Chloride and N-Methylpyrrolidone;
Regulation of Certain Uses Under TSCA § 6(a)

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers and users of methylene chloride (dichloromethane or DCM). We offer these comments on EPA's proposed rule banning manufacture of DCM for and use of DCM in consumer and most types of commercial paint and coating removal. 82 Fed. Reg. 7464 (Jan. 19, 2017); 82 Fed. Reg. 20310 (May 1, 2017). This rule, proposed under § 6(a) of the Toxic Substances Control Act (TSCA), is based on a Work Plan Assessment of DCM completed by EPA in August 2014. TSCA was amended in June 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act").

While EPA is authorized under new TSCA § 26(l)(4) to propose a § 6 rule based on a risk assessment completed before TSCA was revised, there is no requirement or deadline for it to do so. Thus, EPA's progress in meeting the ambitious goals of the Lautenberg Act will in no way be impeded by deliberate review of the subject proposal. The situation is very different for the ten priority compounds recently designated by EPA under TSCA § 6(b)(2)(A).[1] For these ten designated pollutants, TSCA establishes deadlines for risk assessments to begin later this year and a schedule for rulemakings. DCM is one of these priority compounds.

Because this is only a proposed rule, subject to no statutory mandate or deadline, its devastating impact on consumers and small businesses can be easily avoided simply by EPA not taking action to adopt it and instead reviewing the paint stripping use as part of the upcoming assessment. This approach will allow serious data quality concerns with the August 2014 Work Plan Assessment to be addressed. Moreover, "EPA intends to issue a separate proposal on methylene chloride in paint and coating removal in commercial furniture refinishing, but plans to issue one final rule covering both this proposal and the future proposed rule on methylene chloride in paint and coating removal in commercial furniture refinishing."[2] Thus, the approach we recommend will not cause delay, as convening stakeholder meetings, issuing a new proposed rule, and further analysis of cost

[1] Designation of Ten Chemical Substances for Initial Risk Evaluations, 81 Fed. Reg. 91927 (Dec. 19, 2016); Risk Evaluation Scoping Efforts under TSCA for Ten Chemical Substances, 82 Fed. Reg. 6545 (Jan. 19, 2017).

[2] 82 Fed. Reg. 7464, 7465. More specifically, the preamble states: "To learn more about paint and coating removal in furniture refinishing, foreseeable impacts of any proposed regulations, and alternatives to methylene chloride, EPA plans to hold a series of stakeholder meetings. These meetings will focus on current practices related to methylene chloride for paint and coating removal in commercial furniture refinishing; any substitute chemicals or alternative methods currently in use or under development; and current and best practices related to respiratory protection programs and exposure reduction. . . . EPA views this section as an Advanced Notice of Proposed Rulemaking, and intends to issue a Notice of Proposed Rulemaking following the series of stakeholder meetings and further analysis on the cost impacts of regulatory action on this industry. Following that proposal and public comment period, EPA intends to finalize together the regulations proposed and the future proposal related methylene chloride in commercial furniture refinishing." 82 Fed. Reg. at 7497-98.

impacts will clearly take a year or more, by which time the TSCA § 6(b)(2)(A) mandated assessment will be underway. It would be far more efficient to address all the paint stripping uses at one time as part of that assessment. Accordingly, we are also submitting these comments to the appropriate docket for the risk evaluation scoping efforts under TSCA for the ten designated chemicals.

I. Gap Filling Purpose of TSCA

TSCA § 9, as originally enacted and as updated by the Lautenberg Act, requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."[3] Worker and consumer health and safety fall under the jurisdictions, respectively, of the federal Occupational Safety and Health Administration (OSHA) and the federal Consumer Product Safety Commission (CPSC), and use of methylene chloride (dichloromethane or "DCM") in paint stripping is already more than adequately regulated under the Occupational Safety and Health Act and the Federal Hazardous Substances Act. This comprehensive regulatory framework provides adequate protections with respect to the same potential adverse impacts and potential exposure pathways targeted by the current EPA initiative. Taking steps that may lead to the removal of products from the marketplace because workers or consumers failed to comply with these existing requirements is not consistent with TSCA either as initially enacted or as revised.

Indeed, in 1985 EPA initiated a priority review of risks of human cancer from exposures to DCM, using its authority under TSCA § 4(f). As part of its TSCA § 4(f) review, EPA issued an advance notice of proposed rulemaking (ANPR) in which it announced that it would be conducting, in consultation with other federal agencies, a comprehensive and integrated regulatory investigation of DCM.[4] Thereafter, EPA reported on how "the integrated regulatory investigation led to significant exposure reductions in the major chlorinated solvent use applications, and established a precedent for future cooperative regulatory endeavors."[5] The notice indicated that an Interagency Work Group, chaired by EPA's Office of Toxic Substances, had been formed "to determine whether DCM presents a significant risk to human health or the environment, and to determine if regulatory actions are needed to limit exposures to DCM." The notice then described risk management actions completed by each agency, as well as a discussion of ongoing risk control activities.

We were initially given to understand that EPA was pursuing regulation of DCM in paint stripping primarily due to concern about reported fatalities from bathtub refinishing. This is a legitimate concern but, as discussed below, there are much more targeted ways to

[3] TSCA § 9(d).

[4] 50 Fed. Reg. 42037 (October 17, 1985).

[5] 56 Fed. Reg. 24811 (May 31, 1991).

address it than the broad restrictions (in effect a prohibition) being considered by EPA. EPA should carefully consider the recommendations below as to how best to address this concern.

OSHA Regulation of Workplace Exposure

OSHA has regulated occupational exposure to DCM for many years. Following the § 4(f) review, OSHA adopted a standard under § 6(b)(5) of the Occupational Safety and Health Act lowering the workplace exposure limit for DCM from 500 parts per million (ppm) to 25 ppm as an 8-hour time-weighted average (TWA). In addition, it established a short-term (15-minute) exposure limit (STEL) of 125 ppm and an action level for concentrations of airborne DCM of 12.5 ppm (8-hour TWA).[6]

In sum, where DCM is used in paint stripping, exposures must be kept below 12.5 ppm to avoid triggering the action level. There is no basis for EPA to assume that DCM is being used in what would be flagrant violation of the OSHA standard.[7]

CPSC Requirements for Consumer Exposure

There is also a long history of CPSC involvement with DCM, beginning in the mid-1970s. Following the TSCA § 4(f) referral, CPSC adopted cautionary labeling for household products containing DCM, including paint strippers, that would meet or exceed the requirements of the Federal Hazardous Substances Act:

"Front Panel

"CAUTION: Vapor Harmful, Read Other Cautions
and HEALTH HAZARD INFORMATION on Back Panel

"[Or equivalent language]

"Back Panel

"Contains methylene chloride, which has been shown to cause cancer in certain laboratory animals. Risk to your health depends on level and duration of exposure.

"[Or equivalent language]

[6] 29 C.F.R. § 1910.1052; 62 Fed. Reg. 1494 (January 10, 1997).

[7] More recent guidance from OSHA and the National Institute for Occupational Safety & Health, also relevant to consumers as it relates to refinishing of bathtubs, also warns directly about the acute hazard. *Methylene Chloride Hazards for Bathtub Refinishers*, OSHA-NIOSH Hazard Alert (January 2013); https://www.osha.gov/dts/hazardalerts/methylene_chloride_hazard_alert.html.

"[The back panel labeling given above would be placed separately from use precaution information such as the following.]

> "Use this product outdoors, if possible. If you must use it indoors, open all windows and doors or use other means to ensure fresh air movement during application and drying. If properly used, a respirator may offer additional protection. Obtain professional advice before using. A dust mask does not provide protection against vapors. Do not use in basement or other unventilated area."[8]

EPA Regulation

EPA itself, in the years following the § 4(f) review, adopted a number of national emission standards that limit emissions of DCM, which is a Hazardous Air Pollutant (HAP) listed in Clean Air Act (CAA) § 112. These include, notably, National Emission Standards for Organic Hazardous Air Pollutants for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources ("the NESHAP").[9] Under CAA § 112, these standards must ensure an "ample margin of safety to protect public health." Thus, if the risk of concern was significant, EPA would have to adopt more protective standards under the Clean Air Act.

The applicable requirements of the NESHAP are as follows:

> "(a) Each paint stripping operation that is an affected area source must implement management practices to minimize the evaporative emissions of MeCl. The management practices must address, at a minimum, the practices in paragraphs (a)(1) through (5) of this section, as applicable, for your operations.
> (1) Evaluate each application to ensure there is a need for paint stripping (e.g., evaluate whether it is possible to re-coat the piece without removing the existing coating).
> (2) Evaluate each application where a paint stripper containing MeCl is used to ensure that there is no alternative paint stripping technology that can be used.
> (3) Reduce exposure of all paint strippers containing MeCl to the air.
> (4) Optimize application conditions when using paint strippers containing MeCl to reduce MeCl evaporation (e.g., if the stripper must be heated, make sure that the temperature is kept as low as possible to reduce evaporation).
> (5) Practice proper storage and disposal of paint strippers containing MeCl (e.g., store stripper in closed, airtight containers).
>
> (b) Each paint stripping operation that has annual usage of more than one ton of MeCl must develop and implement a written MeCl minimization plan to

[8] Labeling of Certain Household Products Containing Methylene Chloride; Statement of Interpretation and Enforcement Policy (hereafter the "Statement"), 52 Fed. Reg. 34,698 (September 14, 1987).

[9] 40 C.F.R. Part 63, Subpart HHHHHH.

minimize the use and emissions of MeCl. The MeCl minimization plan must address, at a minimum, the management practices specified in paragraphs (a)(1) through (5) of this section, as applicable, for your operations. Each operation must post a placard or sign outlining the MeCl minimization plan in each area where paint stripping operations subject to this subpart occur. Paint stripping operations with annual usage of more than one ton of MeCl, must comply with the management practices in paragraphs (a)(1) through (5) of this section, as applicable, but are not required to develop and implement a written MeCl minimization plan.

(c) Each paint stripping operation must maintain copies of annual usage of paint strippers containing MeCl on site at all times.

(d) Each paint stripping operation with annual usage of more than one ton of MeCl must maintain a copy of their current MeCl minimization plan on site at all times."[10]

It is unclear how action under TSCA realistically could achieve greater public health protection for paint stripping sources of DCM than EPA already is required to achieve under current law.

Requirements of TSCA § 9

TSCA § 9, as amended, provides:

"(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

[10] 40 C.F.R. § 63.11173.

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and
(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

"(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order, within the time period specified by the Administrator in the report, declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or
(B) responds within the time period specified by the Administrator in the report and initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities, the Administrator may not take any action under section 6(a) or 7 with respect to such risk."

(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—(1) The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the actions to be taken under this title and an action to be taken under such other law to protect against such risk."

If this statutory language were not sufficient to express the limitations on EPA's authority, the legislative history leaves no doubt. The House Energy and Commerce Committee Report states: "H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals," and further clarifies that "while section 5 makes no amendment to TSCA section 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety."[11]

Two colloquies on the floor of the House of Representatives make this intent clear with specific reference to the instant rulemaking on methylene chloride. First:

"Mr. SHIMKUS. Mr. Speaker, I yield 2 minutes to the gentlewoman from Tennessee (Mrs. *Blackburn*), the vice chair of the full committee.

Mrs. BLACKBURN. Mr. Speaker, I do rise in support of the amendments to H.R. 2576, and I congratulate Chairman *Shimkus* on the wonderful job he has done. Mr. Speaker, I yield to the gentleman from Illinois (Mr. *Shimkus*) for the purpose of a brief colloquy to clarify one important element of the legislation.

Mr. Chairman, it is my understanding that this bill reemphasizes Congress' intent to avoid duplicative regulation through the TSCA law. It does so by carrying over two important EPA constraints in section 9 of the existing law while adding a new, important provision that would be found as new section, 9(b)(2).

It is my understanding that, as a unified whole, this language, old and new, limits the EPA's ability to promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when the Agency either already regulates that chemical through a different statute under its own control and that authority sufficiently protects against a risk of injury to human health or

[11] H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28.

the environment, or a different agency already regulates that chemical in a manner that also sufficiently protects against the risk identified by EPA.

Would the chairman please confirm my understanding of section 9?

Mr. SHIMKUS. Will the gentlewoman yield?

Mrs. BLACKBURN. I yield to the gentleman from Illinois.

Mr. SHIMKUS. The gentlewoman is correct in her understanding.

Mrs. BLACKBURN. I thank the chairman. The changes you have worked hard to preserve in this negotiated bill are important. As the EPA's early-stage efforts to regulate methylene chloride and TCE under TSCA statute section 6 illustrate, they are also timely.

EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary since its own existing regulatory framework already appropriately addresses risk to human health. New section 9(b)(2) will force the Agency to do just that.

I thank the chairman for his good work."[12]

Second:

"Mr. PITTENGER. Mr. Speaker, I thank the chairman for this very sensible legislation. I appreciate his efforts in leading a bipartisan effort to reform U.S. chemical safety law that is decades in the making.

I particularly thank him for securing amendments to section 9 of the TSCA law that remain in the negotiated text. These amendments reemphasize and strengthen Congress' intent that TSCA serve as an authority of last resort for the regulation of a chemical when another authority under EPA's jurisdiction, or another Federal agency, already regulates the chemical and the risk identified by EPA.

As a unified whole, TSCA now makes clear that EPA may not promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when:

Number one, the agency either already regulates that chemical through a different statute under its own control, like the Clean Air Act, and

[12] 162 Cong. Rec. H3028 (May 24, 2016).

that authority sufficiently protects against a risk of injury to human health or the environment; or

Number two, a different agency already regulates that chemical in a manner that also sufficiently protects against the risk already identified by EPA.

Mr. Speaker, in light of yet another regulatory overreach in the rulemaking at EPA, the new amendments to section 9 of TSCA are a welcome reform with the intent that it will help restrain the agency's unnecessary activities. These are commonsense, but important, protections given what EPA is likely to pursue."[13]

Indeed, TSCA § 9 was strengthened by the Lautenberg Act, and it was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another act is sufficient to regulate a particular risk."[14] EPA applied this statutory directive in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or reduced to a significant extent under the Occupational Safety and Health Act, and referring the matter for action by OSHA.[15] And in an analysis of TSCA § 9, EPA's Acting General Counsel concluded that "Congress expected EPA – particularly where the Occupational Safety and Health Act was concerned – to err on the side of making referrals rather than withholding them."[16]

EPA's Failure to Meet Requirements of § 9

As noted above, OSHA has regulated occupational exposure to DCM for many years. OSHA should be given an opportunity to consider whether a lower workplace standard would be appropriate. Otherwise, if EPA were to go forward with regulation under TSCA, there would be a potential for conflicting and overlapping regulation. OSHA's existing limits would remain in place, regardless of EPA's action, and OSHA's enforcement of its own standards is mandatory (subject to prosecutorial discretion). OSHA may not, however, enforce an EPA regulation under the general duty clause of the Occupational Safety and Health Act, even if the EPA regulation afforded greater protection, as long as an OSHA standard on the same substance is in effect.

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[13] *Id.*

[14] 122 Cong. Rec. H11344 (Sept. 28, 1976).

[15] 50 Fed. Reg. 27674 (July 5, 1985).

[16] Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2.

It is also significant that EPA is not authorized to establish ambient concentration limits under TSCA § 6.[17] EPA thus cannot limit employee exposure directly, but could only do so indirectly, *e.g.,* by controlling the amount of substance used in a product or prohibiting a particular use of the substance under § 6. This is potentially much more burdensome economically than ambient standards, which permit each employer subject to the standards to achieve the necessary reduction in exposure in the most cost-effective manner. Yet TSCA § 6(c)(2) requires EPA carefully to consider the cost effectiveness of a proposed regulatory action against at least one alternative, and Executive Order 13563 requires agencies to achieve their objectives by using the least costly regulatory alternative.[18]

In light of the foregoing, considerations of avoiding unnecessary duplication and utilizing established expertise weigh in favor of invoking the Administrator's referral authority under TSCA § 9(a) even if EPA were to proceed under TSCA. If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.[19]

There is no evidence that EPA has submitted to OSHA or CPSC "a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk and includes in such description a specification of the activity or combination of activities

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[17] H. Rep. No. 1341, 94th Cong., 2d Sess. 34 (1976), *reprinted in* House Committee on Interstate and Foreign Commerce, *Legislative History of the Toxic Substances Control Act*, at 441 (1976)..

[18] Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821-3823 (January 21, 2011). In pertinent part, E.O. 13563 states:

"This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public."

[19] As noted above, § 9(a) provides that if the Administrator has reasonable basis to conclude that an unreasonable risk of injury is presented, and he determines, in his discretion, that the risk may be prevented or sufficiently reduced by action under another federal statute not administered by EPA, then the Administrator shall submit a report to that agency describing the risk. In the report, the Administrator shall request that the agency determine if the risk can be prevented or sufficiently reduced by action under the law administered by that agency; if so, the other agency is to issue an order declaring whether the risk described in the Administrator's report is presented, and is to respond to the Administrator regarding its prevention or reduction. The Administrator may set a time (of not less than 90 days) within which the response is to be made. The other agency must publish its response in the Federal Register. If the other agency decides that the risk described is not presented, or within 90 days of publication in the Federal Register initiates action to protect against the risk, EPA may not take any action under § 6 of TSCA.

which the Administrator has reason to believe so presents such risk." The non-existent report obviously did not "include a detailed statement of the information on which it is based" and was not "published in the Federal Register," as required.

Had the required report been issued, in the case of OSHA it presumably would have identified how OSHA's authority over the workplace was insufficient to address the risks posed by DCM-based paint strippers. A letter from the Assistant Secretary of Labor for Occupational Safety and Health (undated but apparently issued on April 4, 2016) identifying limits on OSHA's authority to regulate hazardous substances such as DCM is included in the docket. This letter does not come close to meeting the requirements of TSCA for EPA action in this case. The April 2016 letter identifies no such gap specific to use of paint strippers in any particular workplace, rather it simply recites how OSHA's authority does not extend to self-employed workers, military personnel, and consumer uses. But those are limitations that were imposed by Congress and have existed since the Occupational Safety and Health Act was enacted. Those limitations apply to every use of every toxic substance. Congress cannot have meant, in enacting "gap-filling" legislation, to open the door to EPA assuming all authority over the use of hazardous substances in the workplace.

Similarly, regarding DCM-based paint strippers sold as household products, EPA action is constrained by the Federal Hazardous Substances Act (FHSA), which grants jurisdiction over household products containing hazardous substances to the CPSC. This jurisdiction is exclusive, excepting only that:

> "The Federal Government and the government of any State or political subdivision of a State may establish and continue in effect a requirement applicable to a hazardous substance for its own use (or to the packaging of such a substance) which requirement is designed to protect against a risk of illness or injury associated with such substance and which is not identical to a requirement described in paragraph (1) applicable to such substance (or packaging) and designed to protect against the same risk of illness or injury if the Federal, State, or political subdivision requirement provides a higher degree of protection from such risk of illness or injury than the requirement described in paragraph (1)."[20]

Under the FHSA, further regulation of these household products is precluded absent a finding that the cautionary language contained in the Commission's Statement is ineffective.[21] The Commission is considering strengthening the label to address the acute

[20] FHSA § 18(b)(2); 15 U.S.C. § 1261n(b)(2).

[21] FHSA § 2(q)(1) defines a "banned hazardous substance" as "any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Commission by regulation classifies as a 'banned hazardous substance' on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under this Act for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only

over-exposure risk that resulted in 14 deaths associated with asphyxiation from use of DCM refinishing bathtubs in spaces with little or no ventilation, and has invited comment on a petition submitted by HSIA.[22] As this was reportedly the initial focus of EPA's concern, it should pay special attention to CPSC's action on the petition, which asks the Commission to expand its 1987 Statement of Interpretation and Enforcement Policy regarding labeling of household products containing DCM so that it addresses acute as well as chronic hazard. A § 6 rule consistent with CPSC efforts with respect to labelling would provide a practical and rational approach to enhancing user awareness and risk avoidance techniques while meeting the amended TSCA standard that EPA select and implement by regulation risk mitigation measures only to the extent necessary so that the targeted chemical substance or mixture no longer presents such risk.

Finally, EPA has not taken into account its own extensive regulation of DCM-based paint stripping under the Clean Air Act. The NESHAP referenced above applies to all area sources engaged in paint stripping using DCM-containing paint strippers, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating operations, except those excluded in 40 C.F.R. § 63.11169(d). This includes virtually the entire universe of small paint stripping operations, as an "area source is defined in the Clean Air Act (CAA) section 112(a) as any stationary source of HAP that is not a major source, and a major source is defined as any stationary source or group of stationary sources located within a contiguous area and under common control that emits, or has the potential to emit, considering controls, in the aggregate, 10 tons per year (tpy) or more of any single HAP or 25 tpy or more of any combination of HAP."[23]

The existence of a comprehensive regulatory framework for paint strippers under the Clean Air Act has two important implications for any consideration of TSCA § 6 rulemaking for the same sector. First, it means that regulation under TSCA § 6 is precluded under TSCA § 9(b) unless EPA can make a determination "that it is in the public interest to protect against such risk by actions taken under this Act," where sponsors of the Lautenberg Act have stated the view that EPA's "own existing regulatory framework already appropriately addresses risk to human health."[24] Second, as described more fully below, the Work Plan Assessment completed by EPA in 2014 is deficient in that it fails to draw on the information available to EPA to evaluate use and exposure information.

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by keeping such substance, when so intended or packaged, out of the channels of interstate commerce." 15 U.S.C. § 1261(q)(1). No such finding has been made for household products containing methylene chloride.

[22] 81 Fed. Reg. 60298 (Sept. 1, 2016). The label submitted by HSIA went beyond precautionary language and stated "Do Not Use To Strip Bathtubs," with a corresponding pictogram. CPSC staff has already approved the expanded cautionary language, which formulators are using (see Appendix 1, attached).

[23] 73 Fed. Reg. 1738 (Jan. 9, 2008).

[24] 162 Cong. Rec. H3028 (May 24, 2016).

II. Failure to Comply with TSCA § 26(l)(4)

With regard to risk assessments completed prior to passage of the Lautenberg Act, including that for DCM, TSCA § 26(l)(4) provides that "the Administrator may publish proposed and final rules under section 6(a) that are . . . consistent with other applicable requirements of section 6." We submit that these include the substantive "best available science" requirements as well as the procedures mandated by statute.

Regrettably, the Work Plan Assessment that is the basis for the proposed rule is, by EPA's own admission, incomplete:

> Following the methylene chloride risk assessment, EPA conducted supplemental analyses to inform risk management. These analyses are consistent with the scope of the methylene chloride risk assessment and were based on the peer-reviewed methodology used in the methylene chloride risk assessment. They included identification of baseline and central tendency exposure scenarios, impacts of reduced methylene chloride content in paint removers, addition of local exhaust ventilation (LEV), use of personal protective equipment (PPE), additional consumer exposure scenarios, and methods of monitoring to determine workplace exposures. The results of EPA's analyses are available in this rulemaking docket (Refs. 19, 20, and 21). Prior to promulgation of the final rule, EPA will peer review the "Respirator and Glove Specifications for Workers Exposed to Methylene Chloride in Paint and Coating Removal," "Supplemental Consumer Exposure and Risk Estimation Technical Report for Methylene Chloride in Paint and Coating Removal," and "Recommendation for an Existing Chemical Exposure Concentration Limit (ECEL) for Occupational Use of Methylene Chloride and Workplace Air Monitoring Methods for Methylene Chloride'' (Refs. 19, 20, 21).[25]

The procedure followed by EPA does not conform to TSCA § 6(b)(4)(H), as added by the Lautenberg Act, which states: "The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation." Further, EPA notes that the supplemental analyses (all dated 2016) have not been peer reviewed. This is a particular concern given EPA's use of the analyses's exposure assumptions to form the basis of its risk management decision in the proposal. A risk assessment must be substantially completed and peer reviewed *before* it is used for risk management decisions, not after those decisions have been made.

In sum, the proposed rule is based on EPA's assumptions that have not been properly vetted through a peer review process. As noted, however, "*proposed* . . . rules under section 6(a)" must be "consistent with other applicable requirements of section 6," including peer review of the underlying science. These procedural shortcomings demonstrate the

[25] 82 Fed. Reg. 7464, 7472.

rushed nature of this rulemaking and strongly support consideration of the paint stripping uses in the context of the upcoming mandated TSCA § 6(b)(2)(A) assessment.

III. Risk Evaluation for DCM in Paint Stripping – Exposure Data Limitations

TSCA § 6(b)(4)(F), as revised by the Lautenberg Act, requires that the risk evaluation, while it may not consider costs or other non-risk factors, must among other things:

- "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;"
- "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance;" and
- "describe the weight of the scientific evidence for the identified hazard and exposure."

New TSCA § 26(h) requires for each risk evaluation (as "a decision based on science") that "the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

> (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
>
> (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
>
> (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
>
> (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
>
> (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models."

Together, these new provisions indicate that a risk evaluation that supports a TSCA § 6 rule must be more robust than the screening level Work Plan Assessment that EPA carried out for DCM. Such an assessment does not meet the requirements of new TSCA § 26(h) nor does it not comply with Office of Management and Budget (OMB) guidelines implementing the Information Quality Act.[26]

The August 2014 assessment uses the incorrect baseline for exposure to DCM from paint stripping, particularly the occupational exposure scenarios. The draft Work Plan assessment itself described the inadequacies of the occupational exposure assessment:

> "The principal limitation of the worker exposure data is the *uncertainty in the representativeness of the data.* EPA reviewed a number of published exposure studies with inherent data limitations including: number of facilities, job sites, or residences; most often, limited number of sites investigated. This reduced information sampling pool introduces uncertainty and precludes EPA from ascertaining whether the observed data are fairly representative of the broad array of possible sites at all geographic locations across the US and for all workers within the particular end-use application. The level of exposure to DCM during stripping processes depends highly on the use of adequate engineering controls (i.e., general and local exhaust ventilation systems) and work practices as seen by the range of exposure data (TNO, 1999). Therefore, these differences can limit the representativeness of any one site with regards to all sites within the specific end-use application. *As a result of these uncertainties, the actual exposure distributions are unknown; the assumed central tendency and high-end exposures may, or may not, fall within the range of exposures estimated for this assessment.*
>
> "An additional data limitation for occupation exposure estimation is the age of the identified exposure studies. *Most of the exposure studies were conducted in the 1990s, with some pre-dating the 1990s; some studies were more recent. Some references have discussed a trend to reduce the use of DCM in paint stripping products (i.e., OSHA promulgated new exposure limits for DCM in 1997). These factors can limit the representativeness of 1990 and older data with regards to present day workplace conditions and exposures.*

[26] First, EPA must conduct a "highly influential scientific assessment" to support TSCA § 6 rulemaking. OMB defines a scientific assessment as "highly influential" if dissemination of the assessment could have a potential impact of more than $500 million in any one year on either the public or private sector, or if the dissemination is novel, controversial, precedent-setting, or has significant interagency interest. The DCM assessment employed worst-case or default assumptions that led to overestimation of potential risks. Such assessments may be appropriate to support a decision that no further action or evaluation is necessary, because there is confidence that the potential risks are not a concern. However, they are inappropriate to support regulations intended to reduce risk because screening level assessments do not accurately estimate risk or quantify exposures. Second, OMB's guidelines also require agencies to subject highly influential scientific assessments to more rigorous peer review. For DCM, EPA selected a contractor to manage the peer review process, even though experts consider contractor-managed peer review to be the least rigorous level of peer review.

As a result of these uncertainties, it is not known, but it is possible, that actual exposure distributions could be declining during the monitoring period considered in this assessment.

"The OSHA IMIS data have the same data limitations as discussed above for the published occupational exposure studies. IMIS data also have additional data limitations to consider. . . ."[27]

While it did not repeat these limitations, the final Work Plan Assessment continued to rely on these data. It is remarkable that EPA would even consider using pre-1997 exposure data in an assessment of occupational exposures to DCM. As noted above, in that year OSHA adopted a standard under § 6(b)(5) of the Occupational Safety and Health Act lowering the workplace exposure limit for DCM from *500* parts per million (ppm) to *25* ppm as an 8-hour time-weighted average (TWA), a 95% reduction. The statement "it is not known, but it is possible, that actual exposure distributions could be declining during the monitoring period considered in this assessment" is puzzling. Entire applications of DCM were lost as a result of the lower workplace limit, in some cases due to substitution by unregulated compounds that, unlike DCM, did pose health risks to the exposed workers. EPA has adopted standards for most of these applications, for which it relied on exposure assessments showing concentrations below 25 ppm.

In sum, where DCM continues to be used, including in paint stripping, exposures must be kept below 12.5 ppm to avoid triggering the action level. There is no basis for EPA to assume that DCM is being used throughout the United States in what would be flagrant violation of the OSHA standard.

Turning to EPA regulation, the response to comments on the draft Work Plan assessment indicates that the NESHAP was taken into account, but the exposure data in the assessment predate the compliance dates of the NESHAP (ranging from January 2008 to January 2011). Most significantly, the assessment seems to have been conducted without reference to the reporting and recordkeeping requirements of the NESHAP. These are extensive. The initial notification must include:

"(1) The company name, if applicable.

(2) The name, title, street address, telephone number, e-mail address (if available), and signature of the owner and operator, or other certifying company official;

(3) The street address (physical location) of the affected source and the street address where compliance records are maintained, if different. If the source is a motor vehicle or mobile equipment surface coating operation that repairs vehicles at the customer's

[27] Draft Work Plan assessment, pp. 65-66 (emphasis added).

location, rather than at a fixed location, such as a collision repair shop, the notification should state this and indicate the physical location where records are kept to demonstrate compliance;

(4) An identification of the relevant standard (i.e., this subpart, 40 CFR part 63, subpart HHHHHH);

(5) A brief description of the type of operation as specified in paragraph (a)(5)(i) or (ii) of this section.

* * * * *

(ii) For paint stripping operations, identify the method(s) of paint stripping employed (e.g., chemical, mechanical) and the substrates stripped (e.g., wood, plastic, metal).

(6) Each paint stripping operation must indicate whether they plan to annually use more than one ton of MeCl after the compliance date.

(7) A statement of whether the source is already in compliance with each of the relevant requirements of this subpart, or whether the source will be brought into compliance by the compliance date. For paint stripping operations, the relevant requirements that you must evaluate in making this determination are specified in § 63.11173(a) through (d) of this subpart. . . .

(8) If your source is a new source, you must certify in the initial notification whether the source is in compliance with each of the requirements of this subpart. If your source is an existing source, you may certify in the initial notification that the source is already in compliance. If you are certifying in the initial notification that the source is in compliance with the relevant requirements of this subpart, then include also a statement by a responsible official with that official's name, title, phone number, e-mail address (if available) and signature, certifying the truth, accuracy, and completeness of the notification, a statement that the source has complied with all the relevant standards of this subpart, and that this initial notification also serves as the notification of compliance status."[28]

Following the initial notification (or subsequent notification of compliance status, if required), annual reports to the permitting authority are required:

"(a) Annual Notification of Changes Report. If you are the owner or operator of a paint stripping, motor vehicle or mobile equipment, or miscellaneous surface coating affected source, you are required to submit a report in each calendar year in which information previously submitted in either the initial notification required by § 63.11175(a), Notification of Compliance, or a previous annual notification of changes report submitted under this paragraph,

[28] 40 C.F.R. § 63.11175.

has changed. Deviations from the relevant requirements in § 63.11173(a) through (d) or § 63.11173(e) through (g) on the date of the report will be deemed to be a change. This includes notification when paint stripping affected sources that have not developed and implemented a written MeCl minimization plan in accordance with § 63.11173(b) used more than one ton of MeCl in the previous calendar year. The annual notification of changes report must be submitted prior to March 1 of each calendar year when reportable changes have occurred and must include the information specified in paragraphs (a)(1) through (2) of this section.

(1) Your company's name and the street address (physical location) of the affected source and the street address where compliance records are maintained, if different.

(2) The name, title, address, telephone, e-mail address (if available) and signature of the owner and operator, or other certifying company official, certifying the truth, accuracy, and completeness of the notification and a statement of whether the source has complied with all the relevant standards and other requirements of this subpart or an explanation of any noncompliance and a description of corrective actions being taken to achieve compliance.

(b) If you are the owner or operator of a paint stripping affected source that has not developed and implemented a written MeCl minimization plan in accordance with § 63.11173(b) of this subpart, you must submit a report for any calendar year in which you use more than one ton of MeCl. This report must be submitted no later than March 1 of the following calendar year. You must also develop and implement a written MeCl minimization plan in accordance with § 63.11173(b) no later than December 31. You must then submit a Notification of Compliance Status report containing the information specified in § 63.11175(b) by March 1 of the following year and comply with the requirements for paint stripping operations that annually use more than one ton of MeCl in §§ 63.11173(d) and 63.11177(f)."[29]

It is remarkable that the Work Plan Assessment was apparently compiled without utilizing the data already in the hands of EPA and other permitting authorities. Moreover, even more extensive information on DCM content and annual usage are required to be maintained by the operators and readily accessible to EPA:

"If you are the owner or operator of a paint stripping operation, you must keep the records specified in paragraphs (e) through (g) of this section, as applicable.

[29] 40 C.F.R. § 63.11176.

* * * *

(e) Records of paint strippers containing MeCl used for paint stripping operations, including the MeCl content of the paint stripper used. Documentation needs to be sufficient to verify annual usage of paint strippers containing MeCl (e.g., material safety data sheets or other documentation provided by the manufacturer or supplier of the paint stripper, purchase receipts, records of paint stripper usage, engineering calculations).

(f) If you are a paint stripping source that annually uses more than one ton of MeCl you are required to maintain a record of your current MeCl minimization plan on site for the duration of your paint stripping operations. You must also keep records of your annual review of, and updates to, your MeCl minimization plan.

(g) Records of any deviation from the requirements in §§ 63.11173, 63.11174, 63.11175, or 63.11176. These records must include the date and time period of the deviation, and a description of the nature of the deviation and the actions taken to correct the deviation.

(h) Records of any assessments of source compliance performed in support of the initial notification, notification of compliance status, or annual notification of changes report."[30]

Conclusion

In sum, the "applicable requirements of TSCA § 6," with which the Lautenberg Act mandates that a completed risk assessment must comply before it can support § 6 rulemaking, include taking into account exposure under the conditions of use, describing the weight of the scientific evidence for the identified hazard and exposure, the use of scientific information, employed in a manner consistent with the best available science, the consideration of variability and uncertainty in the information, and consideration of the extent of independent verification or peer review of the information.

The DCM Work Plan Assessment, on the other hand, is a screening level assessment, its hazard assessment is based on "strength of evidence" as opposed to "weight of evidence," its exposure assessment is based on workplace limits in effect 20 years ago that are 20 times higher than current limits, and ignores available EPA data, and it includes no formal or informal uncertainty analysis. To maintain the credibility of its regulatory efforts under TSCA, it is imperative that EPA build upon available information to construct a realistic risk assessment before proceeding with rulemaking.

[30] 40 C.F.R. § 63.11177.

IV. Risk Evaluation for DCM in Paint Stripping -- Epidemiological Evidence Does Not Support Conclusion that DCM Poses a Cancer Risk

EPA asserts that exposure to DCM can lead to liver, brain, and lung cancer, non-Hodgkin's lymphoma (NHL) or multiple myeloma, and benign mammary tumors. Neither the Work Plan Assessment nor the earlier Integrated Risk Information System assessment of DCM,[31] on which it was based, have seriously addressed the well-conducted worker cohort studies that show no increase in overall cancer incidence or in the specific cancers mentioned above.

The available epidemiology data base for DCM is one of the most robust available for any industrial chemical. Studies of five occupational cohorts are available for the assessment of mortality effects. These include two cohorts of photographic film base manufacturing workers at an Eastman Kodak facility in New York, two cohorts of fiber production employees at plants in Maryland and South Carolina owned by Hoechst Celanese, and a cohort of fiber production workers in the United Kingdom. None of these studies shows an association between increased cancer risk and exposure to relatively high concentrations of methylene chloride.

The cohort studies have many features that make them useful for evaluating potential health effects associated with methylene chloride, including: (i) relatively large study groups with significant numbers of long-term employees; (ii) large numbers of workers with career mean and hourly exposures *above* currently permitted levels; and (iii) lengthy intervals between first exposure and the end of follow-up. In addition, as discussed below, the Eastman Kodak studies contain a detailed exposure characterization allowing dose-response analyses:

> *"Kodak summary.* Collectively, the studies conducted on the Kodak employees exposed to methylene chloride represent one of the best sources of information on the possible human health effects of occupational methylene chloride exposure. Although the early reports did not assess individual workers' methylene chloride exposure, the later updates drew on extensive exposure information. Corroborating the ambient methylene chloride exposure estimates were the biological monitoring of COHb in the blood and carbon monoxide (CO) in expired air (DiVincenzo and Kaplan 1981).
>
> "The more recent updates also provided between 20 and 50 years of follow-up; however, no clear cancer risk or exposure-response effect has been observed. In summary, the Kodak research was well designed, thoughtfully conducted, and appropriately expanded over time. Findings were consistently negative for causes of death hypothesized to be related to methylene chloride exposure, such as ischemic heart disease and cancers of the lung and liver, as well as for

[31] Toxicological Review of Dichloromethane (Methylene Chloride) (CAS No. 75-09-2) in Support of Summary Information on the Integrated Risk Information System (IRIS) (2011) ("IRIS Assessment").

any other specific cause of death. The excess of pancreatic cancer noted for the 1964-1970 cohort followed through 1984 was attenuated upon additional follow-up and was not seen in the overlapping 1946-1970 cohort (Hearne *et al.* 1992b)."[32]

Considered as a whole, the available epidemiological evidence does not indicate a cancer risk associated with occupational exposures to methylene chloride. The studies consistently demonstrate no excess mortality for all causes of death, total cancer, or the cancers that were observed in the one positive mouse bioassay – lung and liver cancers. EPA, as reflected in the 2011 IRIS Assessment, has tended to minimize the contribution of the occupational cohort studies while failing to recognize the weaknesses of the case control studies.[33]

The epidemiology studies also do not support an association between DCM exposure and brain cancer. A study referenced by EPA as "suggestive" evidence for an association between methylene chloride exposure and astrocytic brain cancer is that of Heinemann *et al.* (1994);[34] the association resulted from the exposure matrix developed by the authors that used job codes to estimate whether and to what extent the workers had been exposed to methylene chloride and five other chlorinated compounds. The bases for assigning methylene chloride exposures and the grading of the exposures are not explicit even in the paper dedicated to describing the framework of the job exposure matrix (Gomez *et al.*, 1994),[35] which links a "high probability of exposure" to the occupations of painting, paint or varnish manufacture, ship or boat building and repair, and electronics manufacture. None of these occupations, however, carries a high probability of exposure to methylene chloride. These supposed high-probability occupations are also considered to involve high-intensity exposures as are those in roofing and pharmaceutical manufacture. As expressed in the publication, it appears that exposures to DCM may have been grossly misclassified, which

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[32] Dell, LD, Mundt, KA, McDonald, M, Tritschler II, JP, Mundt, DJ, Critical Review of the Epidemiology Literature on the Potential Cancer Risks of Methylene Chloride, *Int Arch Occup Environ Health* 72: 429-442 (1999).

[33] With regard to animal studies, the EPA IRIS Assessment also erroneously concludes that drinking water bioassays conducted by Kirschman and Serota in the early 1980s for the National Coffee Association are positive, based on the Hazelton laboratory's statistical analysis. Both the study authors and reviewers (including EPA in its earlier assessments) have always considered these studies negative. The Hazelton report states that the incidence of hepatocellular adenomas and carcinomas in treated male mice was slightly higher than controls. It goes on to state, however, that the increase was not dose-related or statistically significant when compared to concurrent controls. Furthermore, the incidence of the lesions in the treated males was well within the historical range of control values both at Hazelton and in the literature. As no treatment-related effects were noted for any of the other endpoints examined, the authors concluded that methylene chloride did not induce a carcinogenic response in male mice, the same conclusion reached for female mice and for rats of both sexes.

[34] Heineman EF, Cocco P, Gomez MR, Dosemeci M, Stewart PA, Hayes RB, Hoar Zahm S, Thomas TL, Blair A Occupational Exposure to Chlorinated Aliphatic Hydrocarbons and Risk of Astrocytic Brain Cancer, *Am J Ind Med* 26: 155-169 (1994).

[35] Gomez MR, Cocco P, Dosemeci M, Stewart PA, Occupational Exposure to Chlorinated Aliphatic Hydrocarbons: Job Exposure Matrix, *Am J Ind Med* 26: 171-183 (1994).

would render the marginal results uninterpretable. Put another way, as described in Norman (1996),[36] the problem with the exposure matrix was that it had exactly reversed the exposure probabilities, so that workers were shown to be widely exposed to carbon tetrachloride, for example, decades after it had ceased being used. The authors acknowledged this mistake, and also acknowledged that in the absence of any direct exposure information, any findings must be interpreted cautiously (Gomez, 1996).[37]

In any event, a recently published comprehensive study of chlorinated solvents and brain cancer found no association between exposure to any of six chlorinated solvents, including methylene chloride, and glioma risk (Ruder *et al.*, 2013).[38] This study specifically referenced Heineman *et al.* (1994), among others, as follows: "Three consecutive case–control studies of glioma and other cause deaths used occupational information from death certificates, next-of-kin interview and job-exposure matrices to estimate solvent exposure with the strongest association for methylene chloride and risk of glioma with increasing probability of exposure and with increasing duration of exposure in high-exposed jobs." "The primary hypothesis was that at least one of these chlorinated solvents would be associated with increased glioma risk." The authors concluded, however, that:

- "In our study of exposure to six chlorinated solvents and glioma, we did not find a higher risk of glioma among solvent-exposed participants"

- "Our results suggest that exposure to chlorinated solvents does not increase the risk of glioma"

- "Study strengths include the large number of histologically confirmed gliomas and the use of population-based controls. Another strength was the estimation of workplace exposure determinants by industrial hygienists blinded to the case–control status of participants, with documented published literature to rigorously estimate intensity. . . . Most of the earlier studies of solvent exposure and brain cancer had greater limitations. Only one previous study included interviews with cases and controls. In the others, occupational information was obtained entirely from cases, from proxies [reference to Heineman *et al.*] or was based on a single occupation on a death certificate."

In conclusion, the absence of associations in well-defined cohorts having experienced high exposures suggests that the carcinogenic hazard of methylene chloride to humans is extremely low or non-existent, as summarized in the review by Dell *et al.*:

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[36] Norman, WC, Flawed Estimates of Methylene Chloride Exposures, *Am J Ind Med* 30: 504-505 (1996).

[37] Gomez MR, Exposure Determinants Needed to Improve the Assessment of Exposure, *Am J Ind Med* 29: 569-570 (1996).

[38] Ruder AM, Yiin JH, Waters MA, *et al.*, The Upper Midwest Health Study: Gliomas and Occupational Exposure to Chlorinated Solvents, *Occup Environ Med* 70: 73-80 (2013).

"No strong or consistent finding for any site of cancer was apparent despite several studies of large occupational cohorts of workers potentially exposed to high concentrations of methylene chloride. Sporadic and weak associations were reported for cancers of the pancreas, liver and biliary passages, breast, and brain. Although these studies collectively cannot rule out the possibility of any cancer risk associated with methylene chloride exposure, they do support a conclusion of no substantive cancer risk."[39]

V. Deficiencies of Cancer Risk Assessment

The cancer risk assessment in the Work Plan Assessment is derived from the 2011 IRIS DCM Assessment, where all the references below may be found. Our principal concerns relate to EPA's interpretations of the data that differ from those of the original study authors, findings of adverse effects that are not supported by the evidence, and application of methodology that is not scientifically justified and led to unreasonably conservative outcomes. Moreover, EPA's characterization of DCM as "likely carcinogenic in humans" is based entirely on the IRIS Assessment, and unfortunately the Work Plan Assessment contains no discussion of concerns raised by HSIA and other commenters on the draft IRIS assessment. Most importantly, the IRIS Assessment used a "strength of the evidence" approach, whereas TSCA § 26(i) expressly requires "decisions under sections 4, 5, and 6 [to be] based on the weight of the scientific evidence."

A. Cancer Classification

In the IRIS Assessment, EPA concluded that DCM was "likely to be carcinogenic in humans" based predominantly on evidence of carcinogenicity at two sites in two-year bioassays in male and female $B_6C_3F_1$ mice (liver and lung tumors) with inhalation exposure and at one site in male $B_6C_3F_1$ mice (liver tumors) with drinking water exposure. As discussed above, considered as a whole the available epidemiological evidence does not indicate a cancer risk associated with occupational exposures to DCM. In general, EPA has tended to criticize the contribution of occupational cohort studies and has failed to acknowledge, in full, the weaknesses of the case control studies. As noted, Heinemann *et al.* (1994) is regarded as "suggestive" evidence for an association between DCM exposure and astrocytic brain cancer, but the job exposure matrix upon which exposures are assessed in this study is not correct.

The bases for assigning DCM exposures and the grading of the exposures are not explicit even in Gomez *et al.*(1994), the paper dedicated to describing the framework of the job exposure matrix, where a "high probability of exposure" was linked to the occupations of painting, paint or varnish manufacture, ship or boat building and repair, roofing, and electronics manufacture. Scoping data recently submitted to EPA demonstrate that these are

[39] Dell, LD, Mundt, KA, McDonald, M, Tritschler II, JP, Mundt, DJ, Critical Review of the Epidemiology Literature on the Potential Cancer Risks of Methylene Chloride, *Int Arch Occup Environ Health* 72: 429-442 (1999).

not occupations carrying a high probability of exposure to DCM.[40] Thus, it appears that exposures to DCM may have been grossly misclassified, resulting in an over-interpretation by EPA of results for brain cancer in the studies reported by Tomenson *et al.* (1997) and Hearne and Pifer (1999) where a small number of brain cancers show SMRs greater than one but, in both cases, the 95% confidence intervals include the null.

The lack of consistency and absence of associations in well-defined cohorts having experienced high exposures suggest that DCM does not present a cancer hazard to humans. It should not be classified as "likely carcinogenic in humans."

B. Non-Genotoxic Mode of Action in Mice

State-of-the-art approaches, involving transcriptomics and PBPK modeling, have provided data which challenge EPA's position that DCM causes cancer in the lungs and liver of laboratory mice through a mutagenic/genotoxic mode of action. As partial justification for the current proposed rule, potential inhalation cancer risks resulting from occupational exposure to DCM have been estimated in the Work Plan Assessment using the inhalation unit risk (IUR) value derived in the IRIS Assessment. That IUR is based on a two-year inhalation study in $B_6C_3F_1$ mice where lung and liver tumors were observed following exposure to DCM concentrations of 2000 and 4000 ppm. As stated in the IRIS Assessment (Section 4.7.3.1), EPA's position is that DCM is carcinogenic through a mutagenic mode of action mediated through the enzyme (or group of enzymes) known as glutathione S-transferases (GSTs):

> "The hypothesized mode of action for dichloromethane-induced lung and liver tumors is through a mutagenic mode of carcinogenic action. Key events within this mode of action are (1) dichloromethane metabolized via GST metabolism, with increasing metabolism through this pathway as exposure levels increase above the saturation of CYP2E1; (2) reaction of GST-pathway metabolites with DNA, leading to (3) mutations in critical genes resulting in tumor initiation; and (4) tumor growth promoted by unidentified molecular or cellular events. Metabolism by CYP2E1, which is more predominant at lower exposures (or tissue concentrations) than metabolism by GST, is considered a protective mechanism against the formation of putatively carcinogenic metabolites from the GST pathway."

This hypothesized mutagenic/genotoxic mode of action, based on a weight of evidence evaluation, has been used by EPA as justification for (i) use of linear low-dose extrapolation in evaluating the dose-response relationship between exposure to DCM and the probability of exposed individuals developing lung and/or liver cancer, and (ii) application of an age-dependent adjustment factor (ADAF). According to EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens, those exposed to

[40] The availability of these data, in docket ID EPA-HQ-OPPT-2016-0742, support our recommendation that risks from the paint stripping uses should be assessed as part of the mandated upcoming assessments under TSCA § 6(b)(2)(A).

carcinogens with a mutagenic mode of action are assumed to have increased early-life susceptibility.

A recent study, sponsored in part by HSIA, provides evidence which challenges the mode of action described above and raises serious questions about the appropriateness of EPA's IUR value. The findings from the study have been accepted for publication in Toxicology and Applied Pharmacology. The abstract from the in-press publication states:

> "Dichloromethane (DCM) is a lung and liver carcinogen in mice at inhalation exposures ≥ 2000 ppm. The modes of action (MOA) of these responses have been attributed to formation of genotoxic, reactive metabolite(s). Here, we examined gene expression in lung and liver from female B6C3F1 mice exposed to 0, 100, 500, 2000, 3000 and 4000 ppm DCM for 90 days. We also simulated dose measures - rates of DCM oxidation to carbon monoxide (CO) in lung and liver and expected blood carboxyhemoglobin (HbCO) time courses with a PBPK model inclusive of both conjugation and oxidation pathways. Expression of large numbers of genes was altered at 100 ppm with maximal changes in the numbers occurring by 500 or 2000 ppm. Most changes in genes common to the two tissues were related to cellular metabolism and circadian clock. At the lower concentrations, the changes in metabolism related genes were discordant - up in liver and down in lung. These processes included organelle biogenesis, TCA cycle, and respiratory electron transport. Changes in circadian cycle genes - primarily transcription factors - showed strong concentration-related response at higher concentrations (Arntl, Npas2, and Clock were down-regulated; Cry2, Wee1, Bhlhe40, Per3, Nr1d1, Nr1d2 and Dbp) were upregulated) with similar directionality in both tissues. Overall, persistently elevated HbCO from DCM oxidation appears to cause extended periods of hypoxia, leading to altered circadian coupling to cellular metabolism. The dose response for altered circadian processes correlates with the cancer outcome. We found no evidence of changes in genes indicative of responses to cytotoxic, DNA-reactive metabolites."[41]

These findings suggest that EPA should, at a minimum, conduct another weight of evidence evaluation on the mode of action by which DCM produces lung and liver tumors in mice. If, as it appears, the study provides support for a threshold dose-response relationship involving CO production and hypoxia, EPA's reliance on the current IUR in evaluating the cancer potential of occupational exposure to DCM would be inappropriate.

C. Occupational Cancer Risks from DCM Appear Manageable

Tables 3-18 through 3-26 from the DCM Work Plan Assessment provide lifetime incremental cancer risk estimates for nine occupational categories. For each job category,

[41] Andersen, M.E., Black, M.B., Campbell, J.L., Pendse, S., Clewell, H.J., III, Pottenger, L.H., Bus, J.S., Dodd, D., Kemp, D. and McMullen, P.D., Combining transcriptomics and PBPK modeling indicates a primary role of hypoxia and altered circadian signaling in dichloromethane carcinogenicity in mouse lung and liver, Toxicol. Appl. Pharmacol., xxx, xxx-xxx (In Press) (2017).

four different exposure scenarios, representing highest to lowest exposures, were evaluated, including:

- Scenario 1. No respirator [high-end exposure frequency (250-d/yr) for 40-yrs]
- Scenario 3. Respirator-APF 25 [high end exposure frequency (250-d/yr) for 40-yrs]
- Scenario 15. Respirator-APF 25 [midpoint exposure frequency (125-d/yr) for 20-yrs]
- Scenario 16. Respirator-APF 50 [midpoint exposure frequency (125-d/yr) for 20-yrs]

According to EPA risk assessment guidance, lifetime incremental cancer risk estimates should only be expressed to one significant figure, so values presented in the Work Plan Assessment should be rounded up or down consistent with that practice. The Human Health Risk Characterization Summary (Section 3.4.4), summarizes the results of the occupational cancer risk evaluation as follows:

> "Many of the occupational scenarios exceeded the target cancer risks of 10^{-6}, 10^{-5} and 10^{-4} when workers employed at various industries handled DCM-paint strippers for 250 days/year for 40 years with no respiratory protection. Adequate respiratory protection and reduced exposure conditions (e.g., exposure to 125 day/year for 20 years) resulted in reduced cancer risks for workers when compared to conditions of no respiratory protection while working with paint strippers for a 250 days/year for a working lifetime (i.e., 40 years)."

This summary overstates the potential cancer risk from DCM. Typically, cancer risks for workers are not considered to be problematic unless they exceed 10^{-4}, with 10^{-6} considered to be a *de minimis* or negligible risk level.[42] Examination of the lifetime incremental cancer risks in Tables 3-18 through 3-26 show that none of the values in Scenarios 15 and 16 exceed 10^{-4} and, for Scenario 3, only four exposures barely exceed 10^{-4} (three at 2×10^{-4} and one at 4×10^{-4}). It is perhaps not surprising that many of the lifetime incremental cancer risk estimates under Scenario 1 exceed 10^{-4}, given that it represents a 40-yr exposure to DCM (250-d/yr) *without* respiratory protection. These results from the DCM Work Plan Assessment indicate that potential cancer risks for commercial users of DCM are certainly manageable with the appropriate worker protection strategies that already exist.

VI. Deficiencies in the Assessment of Non-Cancer Hazards

A. Inhalation Hazard Values

Since the EPA IRIS program began in 1985, it has focused on the development of chronic hazard information based on both carcinogenic and non-carcinogenic endpoints. With the initial Work Plan Assessments, including the DCM Assessment, there has been an

[42] EPA Office of Pesticides and Toxic Substances, The Delaney Paradox and Negligible Risk, Environmental Fact Sheet, Washington, DC (1990).

increasing Agency emphasis on acute inhalation exposures under residential, consumer, and occupational scenarios. The DCM Work Plan Assessment, for example, evaluates residential non-cancer risks for five different exposure durations (*i.e.*, 10-min, 30-min, 1-hr, 4-hr and 8-hr) and occupational non-cancer risks for one exposure duration (*i.e.*, 8-hr). Unfortunately, the IRIS program has not developed the hazard information needed to evaluate acute exposures, creating a situation where other, often inappropriate, hazard data are used to drive risk management decisions that can have serious social and economic implications for a chemical like DCM.

In the DCM Assessment, for example, acute risk estimates for *residential* exposures to DCM-based paint strippers (≤1-hr) were evaluated using Spacecraft Maximum Allowable Concentrations (SMACs) and Acute Exposure Guidelines (AEGLs).

SMACs are guideline values set by the NASA/JSC Toxicology Group in cooperation with the National Research Council Committee on Toxicology (NRCCOT). According to NASA/JSC these values:

> "should not be used for situations other than human space flight without careful consideration of the criteria used to set each value. The SMACs take into account a number of unique factors such as the effect of space-flight stress on human physiology, the uniform good health of astronauts, and the absence of pregnant or very young individuals. . . . . Short-term (1 and 24 hour) SMACs are set to manage accidental releases aboard a spacecraft and permit risk of minor, reversible effects such as mild mucosal irritation."[43]

EPA introduced a UF of 10 to the DCM SMAC value, presumably to address differences between astronauts and the general population, but we remain very concerned both with this unprecedented and non-recommended application of SMACs and with the use of any values that were established/last reviewed 25 years ago (in 1992).

AEGLs are emergency response values designed for rare exposures to airborne chemicals and are used by emergency planners and responders as guidance in dealing with rare, usually accidental, releases of chemicals into the air to support determination of evacuation strategies. AEGLs were originally set by the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee). The last meeting of the NAC/AEGL Committee was in April 2010 (its charter expired in October 2011) and although the work of the NAC/AEGL Committee ended, the program apparently continues to operate at some level within EPA.

HSIA has two concerns about EPA's reliance on AEGL values to evaluate non-cancer risks from DCM. First, the DCM Assessment does not make clear that the AEGL values used are actually "interim" values, which have not been subjected to a thorough peer review process. According to the EPA AEGL website:

[43] NASA/JSC, Spacecraft Maximum Allowable Concentrations for Airborne Contaminants, Publication JSC 20584, National Aeronautics and Space Administration, Space and Life Sciences Directorate, Houston, TX (1999).

"Interim AEGLs are established following review and consideration by the National Advisory Committee for AEGLs (NAC/AEGL) of public comments on Proposed AEGLs. Interim AEGLs are available for use by organizations while awaiting NRC/NAS peer review and publication of Final AEGLs. Changes to Interim values and Technical Support Documents may occur prior to publication of Final AEGL values."[44]

A second concern relates to the AEGL-2 values used in the DCM Assessment. Interim AEGL-2 values are provided for exposure periods of 10-min, 30-min, 1-hr, 4-hr and 8-hr, but they are based on two different non-cancer endpoints. The first two (*i.e.*, 10-min and 30-min) are based on CNS effects, while the other three are based on the formation of a specific level (*i.e.*, 4%) of COHb. This disparity would certainly appear to complicate any judgment about the potential for DCM to cause non-cancer effects in a dose-related manner. For example, are the risks from CNS effects that occur following a 1-hr exposure to DCM more or less severe than the generation of a specific level of COHb between 1 and 8 hours?

Overall, it appears that, in the absence of peer-reviewed, nationally-recognized acute hazard values for DCM, the Work Plan Assessment has used whatever values it could find to evaluate potential acute non-cancer risks. This is not an example of using the best available science, and results generated using these values must be viewed with caution.

B. Margin of Exposure

A margin of exposure (MOE) approach has been used in the DCM Work Plan Assessment to evaluate non-cancer risks associated with various acute and chronic exposure scenarios. Although this appears to be the approach that EPA prefers, it does present difficulties when trying to identify exposure scenarios that might require risk management and also leads to a lack of transparency.

The MOE approach makes use of the Point of Departure (POD). In deriving a hazard value from an animal study under the IRIS program, for example, EPA would use benchmark dose evaluation software to generate the POD based on the dose-response data and would then apply one or more uncertainty factors (UFs) to derive the reference concentration (RfC). With DCM, for example, the POD determined under IRIS was 17.2 mg/m^3 and UFs totaling 30 were applied to yield the RfC of 0.6 mg/m^3. To determine the MOE, the POD would be divided by the measured/modeled air concentration of DCM under a given exposure scenario and as long as that value was ≥30 (*i.e.*, the benchmark MOE), there would not be any non-cancer risk concern.

Where this can become problematic from a transparency perspective is illustrated with California OEHHA's reference exposure level (REL) for DCM.[45] OEHHA has published an acute (*i.e.*, 1-hr) REL of 14 mg/m^3 as well as a chronic REL of 0.4 mg/m^3. The

[44] https://www.epa.gov/aegl/about-acute-exposure-guideline-levels-aegls

[45] OEHHA (Office of Environmental Health Hazard Assessment), Acute Reference Exposure Level (REL) and Toxicity Summary for Methylene Chloride, California Environmental Protection Agency, Sacramento, CA (2008).

acute REL was based on a 1976 study summarized below,[46] and employed a UF of 60. As a consequence the DCM Assessment uses an acute POD of 840 mg/m^3 (*i.e.*, REL x UF) to evaluate the MOE and sets 60 as the Benchmark MOE.

> "In twelve healthy adult volunteers exposed to 195 ppm (680 mg/m^3) MC [DCM] (Putz *et al.*, 197[9]), significant decrements in performance were first noted after 90 minutes of exposure with increasing decrements in performance observed after prolonged exposure. Blood COHb levels rose from 1.35% pre-exposure to 5.1% post-exposure. No subjective symptoms, such as headache, nausea, or irritation of the nose and throat were reported. The 90-minute exposure to 195 ppm MC [DCM] is a LOAEL. An uncertainty factor of 6 was applied to the LOAEL to develop a NOAEL and a factor of 10 was applied to the NOAEL to account for individual variability in response. An equivalent 60-minute exposure was estimated from the 90-minute exposure using the equation Cn * T = K, where n = 2."

Although California OEHHA has only developed and published acute and chronic RELs, Table 3-10 in the Work Plan Assessment lists an 8-hr REL POD (290 mg/m^3) attributed to OEHHA. If this value was actually calculated by EPA, attribution should not be given to OEHHA, and a detailed description of the process followed in deriving it should be provided in the Assessment.

Table 3-17 of the Work Plan Assessment provides a further example of the transparency issues with the MOE approach. That table summarizes acute non-cancer risks for DCM exposure under several occupational scenarios. Two 8-hr PODs are used to evaluate these potential risks, the REL POD of 290 mg/m^3, just described, and the AEGL-2 POD of 210 mg/m^3. At first glance, there appears to be fairly good agreement between the two values, however, the Benchmark MOE for the REL POD is 60 while the Benchmark MOE for the AEGL-2 POD is 1. With the former, an MOE $\leq$60 might be of risk concern; with the latter, an MOE $\leq$1 might be of risk concern. In risk assessment guidance under the EPA Superfund program, non-cancer inhalation risks were evaluated using a hazard quotient (HQ) approach. The HQ was simply the ratio of the exposure concentration and the RfC or, in this case, the REL (both of which were derived using UFs). Exposures resulting in HQ values $\leq$1 were not considered to be of risk concern, making it easy to scan tables and identify exposure scenarios that might be of concern (*i.e.,* HQ's >1.0).

The design of the DCM Assessment itself introduces an unnecessary level of complexity into the evaluation of potential risks resulting in transparency issues. As summarized in Appendix 2 (attached), a total of 302 individual exposure scenarios of non-cancer DCM risks were evaluated in the Work Plan Assessment. Each of these 302 scenarios was subjected to an MOE evaluation resulting in a 'risk/no risk' determination feeding into the risk management decision process. Such complexity in the evaluation of DCM does not seem to be warranted.

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[46] Putz, VR, Johnson, BL, Setzer, JV, A Comparative Study of the Effects of Carbon Monoxide and Methylene Chloride on Human Performance, *J. Environ Pathol Toxicol* 2(5): 97-112 (1979).

C. Inhalation Reference Concentration (RfC)

HSIA considers "hepatocyte vacuolation" in the long term inhalation study in Sprague-Dawley rats to be an inappropriate end-point for EPA's calculation of an RfC.

As part of the IRIS Assessment, EPA reviewed the evidence for liver effects in workers exposed to high levels of DCM by inhalation and found no convincing adverse effects. Also, the "animals with hepatocyte vacuolation" designation in the Nitschke *et al.* (1988a) study[47] may well represent effects of low toxicological concern (note 59% incidence in control females). Since it seems unlikely that DCM at low dose levels will induce effects in the human liver, there may be more appropriate end-points for setting an RfC, such as the increase of carboxyhemoglobin (COHb) that results from DCM metabolism via the CYP2E1 pathway. The standard for carbon monoxide itself could be used and the exposure to DCM that *adds* COHb equivalent to the CO standard could be back-calculated to yield an RfC. This calculation would have the advantages that information from human studies only would be required, and the generation of COHb is considered an effect of significance in humans. This approach would certainly be supported by the transcriptomics findings from the HSIA-sponsored study described earlier in Section V(B) above (Andersen *et al.* (2017)).

It is important to note that the chronic inhalation RfC is not an appropriate health standard for evaluation of potential occupational health risks of DCM. The chronic inhalation RfC is designed to reasonably protect the general population (including susceptible groups such as youth and elderly generally not in the workplace) exposed to DCM from any and all inhaled DCM exposures. Correction of workplace exposures to average daily exposures or lifetime average daily exposures (*see* Table 3-12, Work Plan Assessment) overlooks the fact that occupational exposure limit values are constructed to address health concerns associated with time-weighted average and/or short-term peak exposures occurring during the working day. Averaging such exposures over the course of an entire day or over an entire lifetime for non-carcinogenic endpoints defeats the purpose of assuring that occupational exposure limits will protect workers from shorter-term (daily 8 hr work shifts) but potentially higher exposures.

VII. Benefits of DCM-Based Paint Strippers

The Agency's proposed rule also fails to meet the requirements of TSCA § 6(c)(2)(A) which requires that EPA consider fully the benefits of chemical products it seeks to prohibit in one or more conditions of use. Many small business participants at the SBAR submitted information demonstrating that DCM-based formulations are the most efficient and cost-effective paint remover products available at retail. Equally, they submitted information demonstrating that the alternative paint strippers currently available in the retail market do not work effectively. Only by ignoring these submissions was EPA able to conclude, incorrectly, that alternative products are technically and economically feasible.

[47] Nitschke, KD, Burek, JD, Bell TJ, Kociba, RJ, Rampy, LW, McKenna, MJ, Methylene chloride: a 2-year inhalation toxicity and oncogenicity study in rats, *Fundam Appl Toxicol* 11: 48-59 (1988).

Moreover, the flammability risk of alternative products has been well documented in this rulemaking. For example, the CPSC advised EPA that:

> "Changes to the availability of this product [DCM-based paint removers] for consumer use and the use of alternatives that may present different acute hazards must be carefully considered. The use of more flammable coating removers may present the potential for a greater fire risk, loss of furnishings, and risk of injury to consumers."[48]

However, EPA did not assess the comparative fire risks of DCM-based products and alternatives, dismissing such an assessment as "impracticable."[49] Rather, EPA asserted that since paint remover products contain multiple chemicals of varying flammability, EPA cannot forecast whether the products that might replace DCM-based products would be more or less flammable. This ignores the history of the market, where DCM-based products became dominant because they are not flammable.

As noted, EPA was advised by the CPSC that banning consumer use of DCM-based paint strippers could increase use of more flammable alternative products. The Agency did not act on this warning. We submit that EPA has failed to meet its obligations under TSCA §26 to use the best available by science by failing to heed this warning and by proceeding with a rulemaking that fails to take into account the documented greater flammability risk posed by alternative products.

VIII. Consideration of Alternatives

TSCA § 6(c)(2)(C), as added by the Lautenberg Act, provides:

"(C) CONSIDERATION OF ALTERNATIVES.—

> "Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect."

[48] EPA-HQ-OPPT-2016-0231-0154 at 3.

[49] 82 Fed. Reg. 7464, 7487.

EPA's proposed ban is predicated on its conclusion that there are viable alternatives to DCM in most paint stripping applications. During the June 2016 Small Business Advocacy Review (SBAR), however, small entity representatives (SERs) provided compelling arguments as to why the available alternatives are not technically or economically feasible. The SERs that formulate *both* DCM-based and non-DCM-based alternatives made clear that, in spite of years of effort to promote the latter, customer acceptance was poor because the alternatives do not effectively strip many substrates. Their statements are more credible than those of SERs trying to market only alternatives.

Following the SBAR, several formulators provided written comments. For example, W.M. Barr noted that customer feedback indicates that paint removal products containing DCM clearly outperform all of the alternatives EPA identified, particularly for consumer, do-it-yourself (DIY), and limited duration use applications. They could identify no alternatively formulated products that quickly, safely, and efficiently remove coatings and substrates in a manner that meets consumer demands. As a result, Barr indicated that it is neither technically nor economically feasible to shift production to an alternative formulation that does not rely on DCM (or NMP).

Barr also summarized testing it had conducted on a variety of coatings and substrates using its formulations and competitors' products as well as certain components and individual ingredients comprising alternative paint removing formulations. The testing indicated that the chemical solvent alternatives such as toluene, acetone, methanol and benzyl alcohol did not completely remove alkyd or epoxy paints in fewer than four hours and in some cases not at all. In contrast, DCM-based products removed both kinds of coatings from substrates within five minutes on all painted surfaces tested, and within 15 minutes on cured coatings.

Barr observed that these findings reflected its experience in the marketplace with alternative formulations that do not contain DCM, noting that it had, on multiple occasions, launched new products with alternative formulations only to find that there was minimal consumer acceptance. Its ultimate customers indicated that the products did not remove all varieties of coatings and did not work as quickly. Barr stated the problem succinctly: "In sum, our experience suggests that users are routinely disappointed by the performance of alternatively formulated products." Obviously, marketing ineffective alternatives that are disappointing to its customers undermines a formulator's credibility and ultimately its brand.

Further, Barr noted that the cost of alternatives can greatly fluctuate with supply conditions. For example, methanol, acetone, and toluene-based paint removers cost approximately the same as DCM-based removers, but are less effective, and will not remove chemically-resistant coatings. In contrast, benzyl alcohol-based products can be two to four times more expensive than DCM-containing products. Prices to consumers for such removers could be as much as $90/gal. versus $22/gal. for DCM-based strippers. And again, such products are less effective, and in some cases completely ineffective, against chemically-resistant paints when compared to DCM-based products.

Similarly, Benco Sales Inc. disagreed with EPA's assessment that there would be cost savings by switching from a DCM-based product, in particular that less product is required because of lower volatility, noting that this does not take into account the reduced effectiveness of other formulations, the need for multiple coatings, the increase in cost, the increase in labor, or the increase in costs for waste removal. Benco stated that costs would increase substantially for every industry sector, and that increased costs and reduced effectiveness would be substantial enough to cause closure of many small businesses.

Finally, the Work Plan Assessment does not consider the significant risks of alternatives in confined spaces used in a similar manner to DCM. Acetone, methanol, and toluene all have exposure concerns. Due to the longer duration necessary to remove coatings, if removal is possible, exposure time necessarily increases, as does the risk of flammability. Properly used, these also require skin, eye, and respiratory protection. EPA acknowledges that it is unable to quantitatively estimate any change in non-cancer risks due to use of substitute chemicals or alternative methods

In sum, the alternatives on the market constitute neither technically nor economically feasible alternatives to DCM-based paint strippers. Given the information EPA has received from the small businesses that rely on and use this chemical, it is clear that a true substitute is not available at this time (and presumably will not be "reasonably available as a substitute when the proposed prohibition or other restriction takes effect").

IX. Conclusion

HSIA urges EPA to assess the risk from the paint stripping use that is the subject of the proposed ban as part of the upcoming assessments mandated for ten priority compounds recently designated by EPA under TSCA § 6(b)(2)(A),[50] which establishes deadlines for risk assessments to begin later this year and a schedule for rulemakings. DCM is one of these priority compounds, so a new risk assessment must be prepared in any event. As noted at the outset, this will not result in any significant delay because EPA intends to issue a separate proposal on DCM in paint and coating removal in commercial furniture refinishing, and then to issue one final rule covering both this proposal and the future proposed rule.[51]

Attachments

[50] 81 Fed. Reg. 91927 (Dec. 19, 2016).

[51] 82 Fed. Reg. 7464, 7465.

APPENDIX 1

U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Carol Afflerbach
Compliance Officer
Division of Regulatory Enforcement
Office of Compliance and Field Operations

Ex. 6 - Personal Privacy

May 26, 2016

Via Certified Mail/caffey.norman@squirepb.com

Caffey Norman
Squire Patton Boggs (US) LLP
2550 M Street, NW
Washington, DC 20037

Re: Cautionary Labeling of Methylene Chloride-Containing Paint Stripper Products

Dear Mr. Norman:

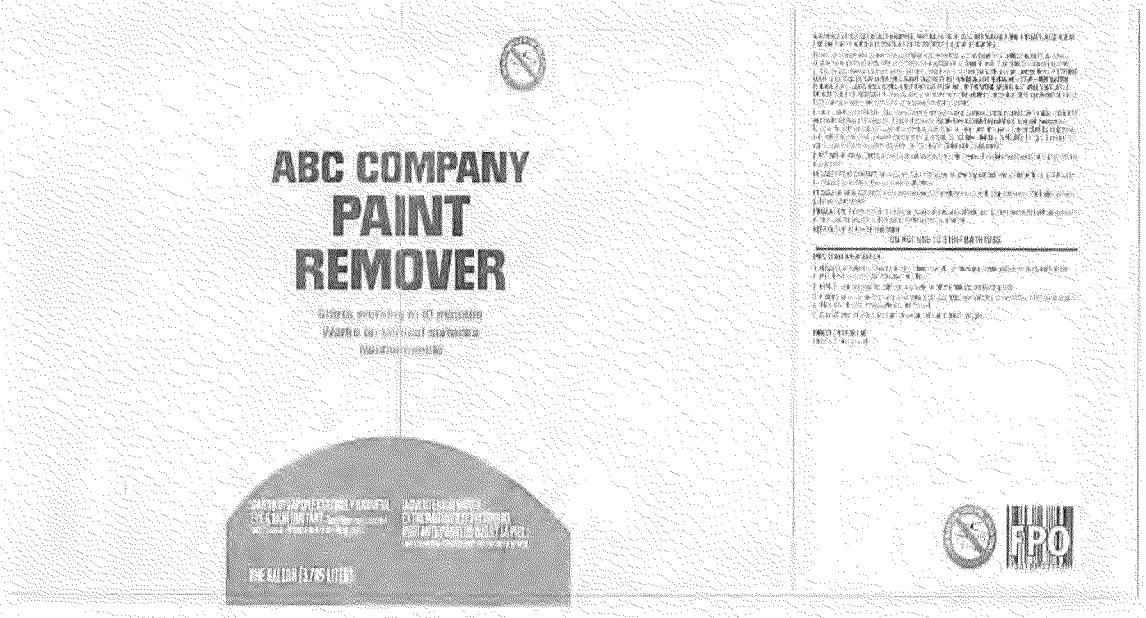
This letter responds to a request by the Halogenated Solvents Industry Alliance (HSIA) that U.S. Consumer Product Safety Commission (CPSC) staff comment on its proposed modified label for methylene chloride-containing paint stripper products under 16 C.F.R. § 1500.128. The proposed label includes enhanced cautionary statements, warning of acute hazards posed with reasonably foreseeable use of methylene chloride-containing paint stripper products in an enclosed space.

On September 14, 1987, the CPSC published a Notice of Interpretation and Enforcement Policy for Labeling of Certain Household Products Containing Methylene Chloride, including paint strippers, which can expose consumers to significant amounts of methylene chloride vapor. *Vol. 52 Federal Register No. 177 Pg. 34698*. The document provided CPSC's recommendations for cautionary labeling to warn consumers of the chronic hazard of carcinogenicity.

The minimum cautionary labeling required under the Federal Hazardous Substances Act (FHSA) is determined by the quantitative formulation of a product and addresses the risk of substantial personal injury or substantial illness during, or as a proximate result of, any customary and reasonably foreseeable use of the product. 15 U.S.C. § 1261(p). The FHSA requires cautionary statements to warn consumers of acute and chronic hazards, to enable consumers to safely use and store the products in and around the household. The recommended cautionary labeling statements for the acute hazards presented in this letter provide CPSC staff's guidance on the specific statements to be used to meet the minimum cautionary labeling requirements of the FHSA.

HSIA submitted the draft label and requested that CPSC staff review CPSC's current labeling guidance for methylene chloride-containing stripper products to address the acute risk of overexposure and to include specific statements indicating that the products are not intended to be used as bathtub strippers. HSIA requested that CPSC staff review HSIA's draft label in response to incidents of accidental death after the products were used to strip bathtubs in bathrooms without adequate ventilation. The deaths occurred from using products that are available to consumers.

Below is the draft cautionary label submitted by HSIA for staff review and comments under 16 C.F.R. § 1500.128:



The cautionary statements on the principal display panel read:

WARNING: VAPOR EXTREMELY HARMFUL
EYE AND SKIN IRRITANT
Read other cautions and health hazard information on back/side panel.

CPSC staff reviewed HSIA's draft label with the minimum cautionary labeling requirements of the FHSA in mind. Based on a product's formulation, a product may require additional principal display panel (PDP) cautionary statements. Due to the reported incidents of death that have occurred over the last 10 years, CPSC staff recommends strengthening the statement of principal hazard to warn consumers that use of the product without adequate ventilation can be fatal. We recommend the following statements:

WARNING: INHALATION OF VAPOR MAY CAUSE DEATH
EYE AND SKIN IRRITANT
Read all cautions on back/side panel.

Below are the remaining back panel precautionary statements and instructions for use:

WARNING! VAPOR EXTREMELY HARMFUL. MAY BE FATAL IF USED IN ENCLOSED AND UNVENTILATED AREAS. USE WITH ADEQUATE VENTILATION TO PREVENT BUILDUP OF VAPORS.

Do not use in areas where vapors can accumulate and concentrate, such as basements, bathrooms, bathtubs, closets, or other small enclosed areas. Whenever possible, use outdoors in an open air area. If using indoors, open all windows and doors, and cross ventilate by moving fresh air across the work area and across the floor**. IF STRONG ODOR IS NOTICED, OR YOU EXPERIENCE SLIGHT DIZZINESS, EYE-WATERING, OR HEADACHE – STOP! VENTILATION IS INADEQUATE. LEAVE AREA IMMEDIATELEY, AND GET FRESH AIR. IF THE WORK AREA IS NOT WELL-VENTILATED, DO NOT USE THIS PRODUCT.** If used properly, a respirator may offer additional protection. Obtain professional advice before using. A dust mask does not provide protection against vapors.

Contains: Methylene Chloride. Methylene Chloride has been shown to cause cancer in laboratory animals. The risk to your health depends on the level and duration of exposure. Reports have associated neurological and other physiological damage to repeated and prolonged overexposure to solvents. Intentional misuse of this product, by deliberately concentrating and inhaling vapors, can be harmful or fatal. Do not take internally. WARNING: Using this product will expose you to chemicals that are known to the State of California to cause cancer.

FIRST AID – IF SWALLOWED, immediately call your poison control center, hospital emergency room or physician for instructions.
IN CASE OF EYE CONTACT, immediately flush with water, remove any contact lenses, continue flushing with water for at least 15 minutes, then get medical attention.
IN CASE OF SKIN CONTACT, irritation may result. Immediately wash with soap and water. If irritation persists, get medical attention.
INHALATION: If inhalation of this material occurs, and adverse effects result, move person to fresh air and keep comfortable for breathing, then get medical attention.
KEEP OUT OF THE REACH OF CHILDREN

DO NOT USE TO STRIP BATHTUBS

IMPORTANT INFORMATION

1. ALWAYS use outdoors, if possible. If using indoors, open ALL windows and interior and exterior doors, and maintain moving fresh air across the workplace and floor.
2. NEVER use in basements, bathrooms, closets, or other small and enclosed spaces.
3. If strong odor is noticed, or you experience slight dizziness, eye watering, or headache, STOP using product and leave work area immediately, and get fresh air.
4. ALWAYS wear chemical-resistant gloves and chemical-splash goggles.

CPSC staff made very few revisions to the HSIA-proposed back panel labeling for methylene chloride-containing paint strippers, and we noted the revisions in the text above. CPSC staff does not have any additional statements to recommend. In addition, the HSIA label proposed the use of a pictogram depicting a bathtub with the prohibition mark through the bathtub. Although the FHSA does not require using pictograms, other than the skull and crossbones, and the special pictogram for charcoal briquette labeling, the FHSA does not prohibit using pictograms. CPSC staff believes that graphics may draw the user's attention to the danger of using the product to strip bathtubs.

Currently, staff does not have plans to recommend that the Commission make changes to the September 14, 1987 Notice of Interpretation and Enforcement Policy or establish mandatory requirements through rulemaking. Under the FHSA, manufacturers must review their product's formulation over time, and adjust the cautionary labeling to best address risks of injury or illness that become known to the manufacturer from using their product. CPSC staff encourages manufacturers to review the cautionary labeling of their methylene chloride-containing paint stripper products, and ensure that adequate labeling is present to address the acute hazards associated with the use of methylene chloride-containing paint strippers and the risk to consumers. Providing a copy of this letter to your members would be helpful to ensure that all manufacturers of methylene chloride paint strippers warn of the hazard of using the paint strippers in enclosed areas.

This letter contains an interpretation by CPSC staff, and has not been reviewed by the Commission. Additional or new information could change our position, and the views could be changed by the Commission.

Please contact me if you have questions about this letter.

Sincerely,

Mary T. Toro for

Carol A. Afflerbach

APPENDIX II

Acute Residential Exposure Scenarios: User & Bystander [10-min, 30-min, 1-hr, 4-hr, 8-hr exposure]

Scenario 1 [Brush application in workshop: central parameter estimates]

Scenario 2 [Brush application in workshop: upper-end user estimates]

Scenario 3 [Brush application in workshop: upper-end user & bystander estimates]

Scenario 4 [Spray application in workshop: central parameter estimates]

Scenario 5 [Spray application in workshop: upper-end user estimates]

Scenario 6 [Spray application in workshop: upper-end user & bystander estimates]

Scenario 7 [Brush application in bathroom: simulation]

Exposures Evaluated = 70 [2-receptors x 5-exposure time periods x 7-scenarios] Sources: Tables 3-15 & 3-16

Acute Occupational Exposure Scenarios [8-hr exposure to Low-Mean-Midpoint-High Air Concentrations]

Professional Contractors

Automotive Refinishing

Furniture Refinishing

Art Restoration & Conservation

Aircraft Paint Stripping

Graffiti Removal

Non-Specific [Immersion Stripping of Wood]

Non-Specific [Immersion Stripping of Wood & Metal]

Non-Specific [Unknown]

Exposures Evaluated = 116 [9-activities x 4-scenarios x 1-4 air concentrations: variable per activity] Source: Table 3-17

Chronic Occupational Exposure Scenarios [8-hr exposure to Low-Mean-Midpoint-High Air Concentrations]

Professional Contractors

Automotive Refinishing

Furniture Refinishing

Art Restoration & Conservation

Aircraft Paint Stripping

Graffiti Removal

Non-Specific [Immersion Stripping of Wood]

Non-Specific [Immersion Stripping of Wood & Metal]

Non-Specific [Unknown]

Exposures Evaluated = 116 [9-activities x 4-scenarios x 1-4 air concentrations: variable per activity]
Sources: Tables 3-27 to 3-25

Total individual non-cancer exposure scenarios evaluated in DCM assessment = 302